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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,417	09/24/2003	Jimin Zhang	THERUS.005CPI	9389

20995 7590 07/31/2007
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EXAMINER	
WEATHERBY, ELLSWORTH	

ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
07/31/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/671,417	Applicant(s) ZHANG ET AL.	
	Examiner Ellsworth Weatherby	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 2,11,21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/25/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1, 3-10, and 12-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Farley et al. (USPN 6,071,277).

Farley et al. '277 teaches a therapeutic medical device adapted to be inserted into a tissue passageway after a percutaneous medical procedure, comprising: a therapeutic medical device adapted to be inserted into a tissue passageway comprising:

a) an elongated shaft having a proximal section, a distal section, a distal tip, at least one lumen, and a second opening on the distal tip in communication with the lumen, wherein the first and second openings and the lumen are configured such that the shaft may be

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threaded over a guidewire extending through the first opening and lumen and out the second opening (col. 17, lines 61-67; col. 18, lines 1-15); b) a means for locating and determining a site at which thermal energy should be applied to promote hemostasis (col. 7, lines 5-20; col. 8, lines 17-23); a means for emitting sufficient thermal energy to the site thereby raising native tissue temperatures and inducing tissue and/or blood coagulation (col. 7, lines 21-55).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 3-7, 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll et al. (USPN 6,083,159) in view of Farley et al. (USPN 6,071,277) and further in view of Martin et al. (USPN 6,007,499).

Driscoll et al. '159 teaches a method for producing hemostasis, tissue closure, and/or vessel closure following a percutaneous medical procedure wherein an access device is introduced to a patient creating a passageway, the method comprising the steps of: a) inserting a probe or catheter to a remote site of internal bleeding, the probe may be inserted transrectally, transvaginally, transesophageally, or the like (col. 8, lines 52-67); b) ultrasonically interrogating a section of the passageway using pulsed Doppler

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(col. 4, lines 23-38); c) advancing the HIFU thermal delivery probe down the passageway until the pulsed Doppler indicates that the probe is at a pre-determined distance from the target site (col. 9, lines 29-42); emitting sufficient thermal energy to the target site in order to raise native tissue temperatures and inducing tissue an/or blood coagulation at the site (claim 12). Driscoll et al. '159 also teaches that the ultrasound transducer is located at a distal end of the thermal delivery probe (col. 7, lines 51-67).

Driscoll et al. '159 does not expressly teach inserting an introducer sheath transcutaneously into an artery, thereby creating the passageway and an arteriotomy. Driscoll et al. '159 also does not expressly teach treating the site of the arteriotomy and that the thermal delivery probe has an outer diameter of about 4-10 French.

In the same field of endeavor, Farley et al. '277 teaches a percutaneous catheter for applying RF energy from an electrode or ultrasound where a percutaneous introducer is inserted into a vein using the old and well-known Seldinger technique. A catheter is passed through the introducer and advanced through the venous treatment site to apply thermal therapy (col. 6, lines 58-67; col. 7, lines 1-20). Farley also teaches that the thermal delivery probe has an outer diameter of about 4-10 French (col. 12, lines 38-63).

Farley et al. '277 does not expressly teach applying thermal energy to the site of the arteriotomy.

Martin et al. '499 teaches using HIFU to treat the site of a hemorrhaging wound where HIFU is applied to the regions of a puncture where the energy exposure causes closure of the wound (col. 4, lines 34-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Driscoll et al. '159 in view of Farley et al. '277 and Martin et al. '499. The motivation to modify Driscoll et al. '159 in view of Farley et al. '277 and Martin et al. '499 would have been to prevent additional tissue damage caused by sliding the catheter through the vessel wall while using the same device to improve the healing time for the patient.

6. Claims 8-9, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Driscoll et al. '159 in view of Farley et al. '277 and Martin et al. '499 as applied to claims 5, 6, 13 and 14 above, and further in view of Unger et al. (USPN 5,558,092).

Driscoll et al. '159 in view of Farley et al. '277 and Martin et al. '499 teach all the limitations of the claimed invention except for expressly teaching that the device is operated at about 6MHz and about 2 W/cm².

Unger et al. '092 teaches a method for performing diagnostic and therapeutic ultrasound simultaneously using an ultrasound transducer array that can operate at about 6MHz (col. 7, lines 60-65) and output about 2 W/cm² (col. 8, lines 37-41).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Driscoll et al. '159 in view of Farley et al. '277 and Martin et al. '499 with Unger et al. '092. The motivation to modify Driscoll et al. '159 in view of Farley et al.

'277 and Martin et al. '499 with Unger et al. '092 would have been to provide therapy within safe and effective operational output ranges.

7. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farley et al. '277 in view of Driscoll et al. '159.

Farley et al. '277 teaches a therapeutic medical device adapted to be inserted into a tissue passageway after a percutaneous medical procedure, comprising: a therapeutic medical device adapted to be inserted into a tissue passageway comprising: a) an elongated shaft having a proximal section, a distal section, a distal tip, at least one lumen, and a second opening on the distal tip in communication with the lumen, wherein the first and second openings and the lumen are configured such that the shaft may be threaded over a guidewire extending through the first opening and lumen and out the second opening (col. 17, lines 61-67; col. 18, lines 1-15); b) a means for locating and determining a site at which thermal energy should be applied to promote hemostasis (col. 7, lines 5-20; col. 8, lines 17-23).

Farley et al. '277 does not expressly teach one or more ultrasound transducers positioned in the elongated shaft; the one or more ultrasound transducers comprising at least one therapeutic ultrasound transducer configured to emit high intensity ultrasound.

Driscoll et al. '159 teaches one or more ultrasound transducers positioned in an elongated shaft; the one or more ultrasound transducers comprising at least one therapeutic ultrasound transducer configured to emit high intensity ultrasound (abstract; fig. 2).

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It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Farley et al. '277 with Driscoll et al. '159 because Farley et al. discloses the use of ultrasound for applying therapeutic energy (col. 6, lines 1-15). The motivation to modify Farley et al. '277 with Driscoll et al. '159 would have been to focus the therapeutic ultrasonic energy to a specific target.

8. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Farley et al. '277 in view of Driscoll et al. '159 as applied to claim 19 above, and further in view of Belef et al. (USPN 6,078,831).

Farley et al. '277 in view of Driscoll et al. '159 teaches all the limitations of the claimed invention except for expressly teaching that the inseratable probe further comprises a diagnostic ultrasound transducer adapted to ultrasonically interrogate a position in front on the elongated shaft distal end.

Belef et al. '831 teaches an ultrasound guide wire having an ultrasound transducer adapted for forward-looking diagnostics (col. 6, lines 42-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Farley et al. '277 in view of Driscoll et al. '159 with Belef et al. '831. The motivation to modify Farley et al. '277 in view of Driscoll et al. '159 with Belef et al. '831 would have been to improve the physician's ability to direct the catheter to the therapy site.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ellsworth Weatherby whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EW


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